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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the ORTHOLOC® 3Di Ankle Plating System.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002
Date:	April 17, 2013
Contact Person:	Ryan Bormann Regulatory Affairs Specialist II Office - (901) 867-4409 Fax – (901) 867-4190
(a)(2). Proprietary Name:	ORTHOLOC® 3Di Ankle Plating System
Common Name:	Bone Plate System
Classification Name and Reference:	21 CFR 888.3030 – Class II
Device Product Code, Device Panel:	HRS: Plate, Fixation Bone
(a)(3). Predicate Device:	K102429 ORTHOLOC® 3Di Ankle Plating System

(a)(4). Device Description

The ORTHOLOC® 3Di Ankle Plating System contains plates belonging to 1 of 2 general categories—distal tibia and fibula—based on the contouring of each plate. All plates feature poly-axial locking screw holes. Some plates have k-wire holes, compression slots, or syndesmosis slots. The plates are made from titanium alloy and accept 2.7mm and 3.5mm ORTHOLOC® 3Di locking screws, 2.7mm, 3.5mm and 4.0mm ORTHOLOC® Bone Screws, and 4.0mm Wright™ Compression Screws (cleared under K082320, now branded DART-FIRE®). Washers are also available for use with the ORTHOLOC® Bone Screws.

The design features of the ORTHOLOC® 3Di Ankle Plating System – Line Addition are substantially equivalent to the design features of the predicate ORTHOLOC® 3Di Ankle Plating System

(a)(5). INTENDED USE

Ankle Plates:
Wright's ORTHOLOC® 3Di Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula such as:

- Lateral Malleolar Fractures
- Syndesmosis injuries
- Medial Malleolar Fractures
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolous
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures

ORTHOLOC® 3Di Locking Screws:
The ORTHOLOC® 3Di locking screws are intended for use with Wright's ORTHOLOC® 3Di Plating Systems of the same base material.

ORTHOLOC® Bone Screws:
ORTHOLOC® Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Washer
Wright's washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of bone fragments.

(a)(6). Technological Characteristics Comparison

The ORTHOLOC® 3Di Ankle Plating System – Line Addition and the legally marketed predicate ORTHOLOC® 3Di Ankle Plating System have identical indications, utilize the same instrumentation, and are identical in material, sterilization methods, and selection.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

- Through mechanical analysis the new plates do not represent a new worst-case.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject line addition can be expected to perform at least as well as the predicate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2013

Wright Medical Technology, Incorporated
% Mr. Ryan Bormann
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K131093
Trade/Device Name: ORTHOLOC® 3Di APS – Straight Tubular Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: April 17, 2013
Received: April 23, 2013

Dear Mr. Bormann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131093 page 1 of 2

Device Name: ORTHOLOC® 3Di APS - Straight Tubular Plates

Indications For Use:

Wright's ORTHOLOC® 3Di Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula such as:

- Lateral Malleolar Fractures
- Syndesmosis injuries
- Medial Malleolar Fractures
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolous
- Pilon Fractures
- Distal Tibia Shaft Fractures
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- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avusion Fractures

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Washer
Wright's washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of bone fragments.

Prescription Use __xxx__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Elizabeth L. Frank -S

Division of Orthopedic Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)
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